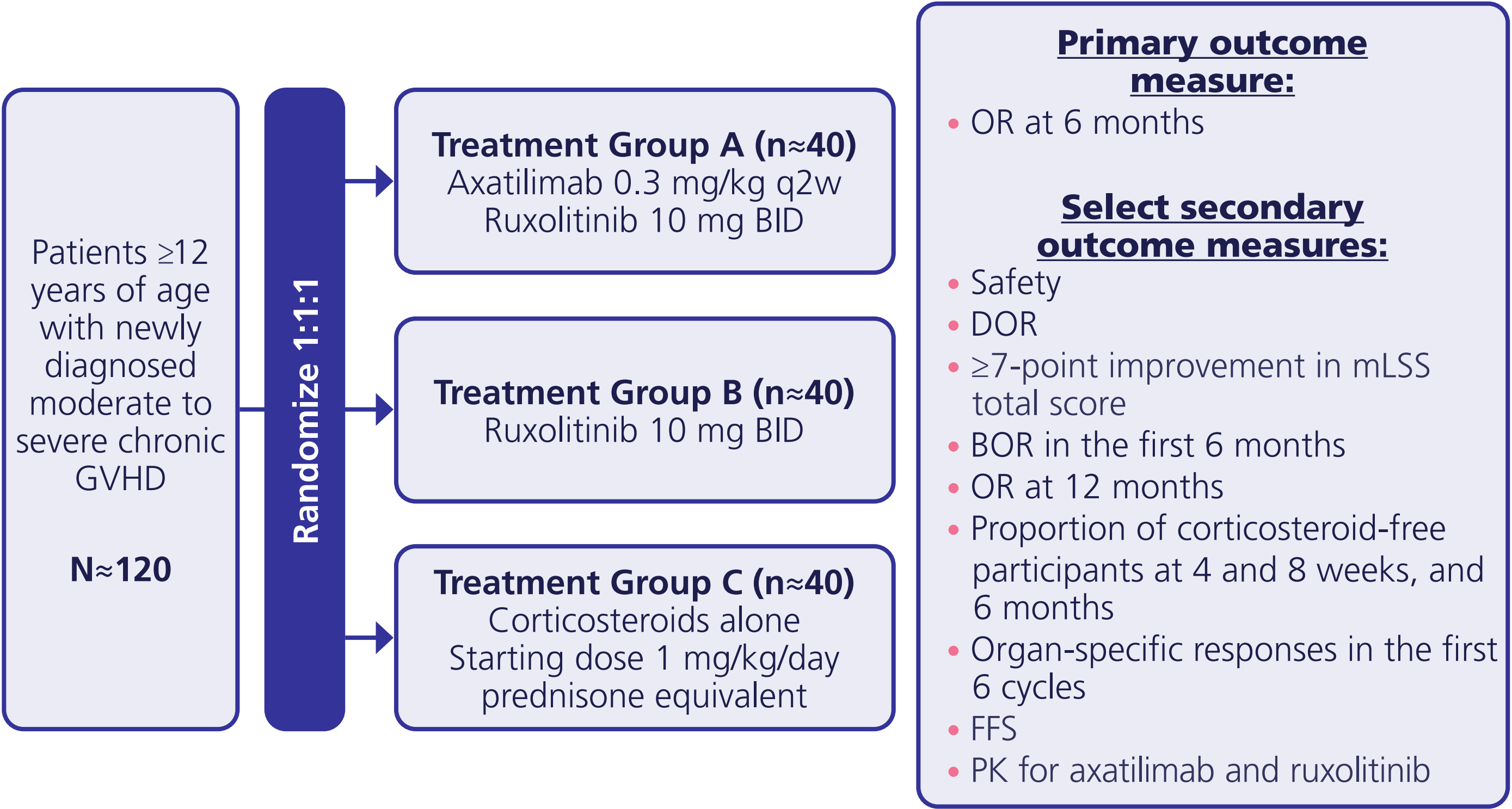


Newly Diagnosed Chronic GVHD

INCA34176-254 | Phase 2 | NCT06388564

Open-Label, Randomized, Multicenter Study of Axatilimab in Combination With Ruxolitinib Versus Ruxolitinib Alone or Corticosteroids Alone^{1,2}



Stratification factors:

- Chronic GVHD severity (moderate/severe)
- Ongoing treatment with a CNI or mTOR inhibitor (yes/no)

Select inclusion criteria:

- Classic chronic GVHD (no features of acute GVHD)
- History of 1 allo-SCT (any type of stem cell donor, any conditioning regimen, and source of hematopoietic stem cells)
- KPS score $\geq 60\%$ if aged 16 years and older; LPS score $\geq 60\%$ if younger than 16 years of age
- Adequate hematologic function independent of platelet transfusion and growth factors for at least 7 days prior to study entry

Select exclusion criteria:

- More than one previous allo-SCT (prior autologous HCT is allowed)
- Previous systemic treatment for chronic GVHD including systemic corticosteroids and ECP
- Initiated systemic treatment with CNIs or mTOR inhibitors within 2 weeks prior to C1D1
- Prior treatment with a JAK inhibitor within 8 weeks before randomization
- Relapsed or progressive primary hematologic disease, or receipt of treatment for relapse after allo-SCT

The use of the compounds including combination use and other manner of treatment discussed are investigational and the efficacy and safety has not been established. There is no guarantee that these compounds will become commercially available for the use(s) under investigation.

For more information, visit [IncyteClinicalTrials.com](https://www.incyteclinicaltrials.com) or contact us at 1-855-4MEDINFO (855-463-3463) or by email at clintrials@incyte.com

Allo-SCT, allogeneic stem cell transplantation; BID, twice daily; BOR, best overall response; C1D1, Cycle 1 Day 1; CNI, calcineurin inhibitor; DOR, duration of response; ECP, extracorporeal photopheresis; FFS, failure-free survival; GVHD, graft-versus-host disease; HCT, hematopoietic cell transplantation; JAK, Januse kinase; KPS, Karnofsky Performance Scale; LPS, Lansky Performance Scale; mLSS, modified Lee Symptom Scale; mTOR, mammalian target of rapamycin; OR, objective response; PK, pharmacokinetic.

1. ClinicalTrials.gov. Accessed July 2024. <https://clinicaltrials.gov/study/NCT06388564>. 2. Data on file, Incyte Corporation.